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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,430	09/22/2003	John F. Shanley	CMI5007USNP1	2375
27777 7590 06/13/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER YABUT, DIANE D				
ART UNIT		PAPER NUMBER		
3734				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,430

Applicant(s)

SHANLEY, JOHN F.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008 and 18 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 31-35 and 40-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28, 31-35 and 40-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 10 recite "the first and second openings containing first beneficial agent" both in the second to last line, and the specification appears to be silent regarding this limitation. Only the first plurality of openings is disclosed as containing the first beneficial agent.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 4-5, 10, 15-18, 20, 23-26, 28, 31-35, 41, 44-45, and 50-53 are rejected under 35 U.S.C. 102(a) as being anticipated by **Hossainy** (U.S. Patent No. **6,558,733**).

Hossainy discloses a stent having a plurality of openings filled with beneficial agents. Specifically, Hossainy discloses a cylindrical device which is expandable, and having end holes at opposite ends of the device, the substantially cylindrical device comprising a plurality of deformable members and non-deformable members, a first plurality of openings containing a first beneficial agent on first and second ends of the cylindrical device; a second plurality of openings containing a second beneficial agent positioned on a central portion of the cylindrical device, wherein the second beneficial agent can be different than the first beneficial agent, wherein the first openings and the second openings are positioned on the non-deformable members. See Hossainy, Figure 4a, col. 5, lines 28-30.

The beneficial agents can comprise different forms of the same drug. See e.g. Hossainy, col. 4, line 41 -col. 5, line 19.

A side hole can be considered to be the circular section that joins adjacent filaments 22 (Applicant's claim 17) in Figure 4a, which has a center axis substantially perpendicular to a longitudinal axis of the device body. Hossainy further discloses

interconnected struts 24 and bridging elements (e.g. 22), and the first and second openings are formed in the struts and bridging elements, respectively or otherwise, depending on which openings are defined as the "first and second" openings. See Fig. 4a.

Hossainy discloses the related method of positioning the device. See col. 3, lines 55-65.

Further, the openings can be different sizes. See col. 5, lines 25-28. The openings can be formed by a laser. See Abstract. The holes can have different shapes. Cf. Figs. 5a-6.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Vallana et al., U.S. Patent No. **6,699,281** ("**Vallana**").

Hossainy does not specifically disclose that the drug itself has a different concentration. However, Vallana discloses that it is well known in the art to implant drugs having different concentrations in a stent. See Vallana, col. 8, lines 15-30; Figs. 10A-10D. Therefore, it would have been obvious to one having ordinary skill in the art

at the time of the invention to vary the concentration, and thus the eluting profile, of the agents within the stent openings.

8. Claims 7-8, 12, and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Welsh et al., U.S. **2005/0278016** ("**Welsh**").

Hossainy does not specifically disclose coating the stent with a third beneficial agent, nor using paclitaxel. However, Welsh discloses that it is well known in the art to coat the stent with a beneficial agent (§ 0144), and that paclitaxel is commonly used as a beneficial agent (§ 0078). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a third beneficial agent on the exterior of the stent, or to use paclitaxel as the first beneficial agent, in view of the teachings of Welsh.

9. Claims 9, 13, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hossainy**, as applied to claims 1, 10, 17, 20, 25, and 41 above, in view of Schreeder et al., U.S. **2002/0007209** ("**Schreeder**").

Hossainy does not specifically disclose using rapamycin. However, Schreeder discloses that it is well known in the art to use rapamycin as a beneficial agent (§ 0152). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use rapamycin as the first beneficial agent, in view of the teachings of Schreeder.

Response to Arguments

10. Applicant's arguments filed 18 January 2008 have been fully considered but they are not persuasive.

11. The applicant generally argues that Hossainy does not disclose providing depots only in one of the filaments or in the interconnecting members, and that Figure 4c shows the exact opposite, since there are depots on both the filaments and interconnecting members. It is noted that the features upon which applicant relies (i.e., having the depots "only in one of the filaments or in the interconnecting depots") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

12. Also, the applicant argues that Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members. The examiner asserts that since the stent moves radially outward, the filaments 24 are less deformable than the interconnecting members 22 (the keyhole-shaped members in Figure 4c that expand outwardly) in the radial direction.

13. The applicant also argues that Hossainy does not disclose a side hole having a center axis substantially perpendicular to a longitudinal axis of the device body, and that holes at the ends of the stent and the lumen itself do not define a side hole. However, the examiner maintains that the side hole can be the circular section that joins adjacent filaments 22 in Figure 4a.

Lastly, applicant argues that the depots 30 in Hossainy are not through openings, and that Hossainy teaches away from the use of through openings. The examiner maintains that openings are considered to be elements that may receive another element -- in the case of Hossainy, the depots receive substances. Also, it is noted that in the specification page 12, paragraph 41 the applicant defines the term "openings" to include both through openings and recesses, and therefore the depots of Hossainy reads on this limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731